Congress of the United States
Washington, DC 20515

October 5, 2022

The Honorable Robert M. Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Commissioner Califf:

We write to you to inquire about future plans to carry out the recommendations highlighted in the recently released internal agency review of the Federal and Drug Administration's (FDA) actions and response to the U.S. infant formula supply shortage.

As you know, in May 2022, more than 40% of the U.S.'s baby formula supplies were out of stock.[1] This infant formula shortage stemmed from the nationwide recall of multiple infant formula products by Abbott, one of the biggest formula producers in the country, and their subsequent shut down of production at one of their largest facilities in Sturgis, Michigan. These actions were taken in response to reports of contaminated formula and the tragic death of two infants due to bacterial infection. While we believe Abbott bears significant responsibility for this issue, we remain concerned by delays at the FDA in responding to reports of these issues. This shutdown and the shortage that followed had far-reaching and catastrophic consequences on families, particularly low-income, minority, and rural families.

Fortunately, we have come a long way since May. After some initial setbacks, the Abbott formula facility in Michigan reopened and resumed production on July 1st. This reopening has eased the shortage and provided parents with greater access to safe infant formula.

We thank you, your colleagues at the FDA, and the Administration for your ongoing efforts to solve this crisis. Following the Sturgis facility shutdown, the FDA's quick collaboration with overseas manufacturers brought safe infant products and formula to American shelves as quickly as possible. This work includes FDA's involvement with Operation Fly Formula, which has already completed over twenty missions and acquired approximately 1.5 million 8-ounce bottles for our families in need. In these ways and more, the Administration has worked to provide infant formula for all families, and we notice their successful efforts in tackling this crisis.

[1] https://www.cnbc.com/2022/05/09/40-percent-of-americas-baby-formula-supplies-are-out-of-stock.html

Still, we cannot forget the tremendous toll that this crisis has had on families in our district and across the nation. At the end of July, 20% of all types of baby formula products were still out of stock. And although this was the lowest rate since early June, this shortage should not have happened, and we must be diligent in working to prevent it from ever happening again.

To this end, we appreciate that the FDA has taken an important first step in prevention by completing an internal review on the agency's actions to address this crisis. Its' findings and recommendations highlighted key systemic vulnerabilities that contributed to this crisis but also important opportunities to strengthen the systems that ensure the safety of our food supply. The five major areas of need and opportunity include (1) modern information technology used for access and exchange of data; (2) staffing, training, equipment, and regulatory authorities; (3) updated emergency response systems; (4) increased scientific understanding about *Cronobacter*, the bacterial contaminant found in the formula; and (5) assessment of the infant formula industry. The identification of these target areas is critical. We are happy to see that the FDA plans to form working groups to implement the recommendations that emerged from these findings and has committed to reporting back on its progress within a year of this evaluation.

As Members of Congress hoping to support these efforts and working to prevent families from being affected by a similar crisis in the future, we respectfully request that the FDA respond to these questions by November 1st, 2022:

- Regarding some of the findings that were highlighted in this report:
    - It was found that a complaint sent via mail and other delivery systems to agency leaders was not delivered and may have delayed the FDA's response to those complaints. How common is it for complaints sent via mail (and other delivery systems) to agency leaders to not be delivered and what steps has FDA taken to improve internal communication?
    - It was also found that samples taken from the Abbott Nutrition facility in Sturgis were delayed in transit. How often are samples enroute to regulatory laboratories delayed in transit? Are there specific circumstances that have led to such delays? What are the impacts of this delay?
    - Investigators were found to have limited infant formula specific training. How did their limited training influence the execution of the investigation? Additionally, are there other critical food product trainings that are underdeveloped or that relevant personnel are not sufficiently briefed on?
- Regarding the recommendations and future actions the FDA has put forth:
    - How will the FDA prioritize addressing these recommendations?
    - Which recommendations will the FDA begin working on immediately, and which recommendations may need Congressional action?
    - Specific to the working groups tasked with implementation:
        - How and under what timeline will these working groups be formed, and under what timeline will the recommendations be implemented?
        - On what regular basis will these working groups report progress to the Commissioner, the Agency Executive Committee, and Congress?

    - Are there any specific goals that the FDA envisions these working groups will/should accomplish?
- More generally, what immediate changes to improve the FDA's emergency response structure have already been implemented?
- Are there any lessons from the FDA's response to the infant formula shortage that it hopes to build on and expand? Could any of these lessons be applied to other areas of the FDA?

We thank you for your attention to this matter and continued commitment to ensuring the safety of our infant formula and general food supply.

Sincerely,

Cynthia Axne
Member of Congress

Mikie Sherrill
Member of Congress

Marie Newman
Member of Congress

Raja Krishnamoorthi
Member of Congress

Susie Lee
Member of Congress

Susan Wild
Member of Congress

Chrissy Houlahan
Member of Congress

Rashida Tlaib
Member of Congress

Brenda L. Lawrence
Member of Congress

Nanette Diaz Barragán
Member of Congress